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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/763,976

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Jerome S. Harms

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7883

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11/02/2006

Frank C. Nicholas  
CARDINAL LAW GROUP  
Suite 2000  
1603 Orrington Avenue  
Evanston, IL 60201

EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/763,976

Applicant(s)

HARMS ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/5/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13-42 is/are rejected.
- 7) ☒ Claim(s) 10-12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

#### **Sequence Rules**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, amino acid sequences are present in Fig. 10, Fig. 12, Fig. 14 and Fig. 16 which are not identified by SEQ ID NO: in the Figures or Brief Description of the Drawings. Any response to this Office Action which does not include complete compliance with the Sequence Rules will be considered non-responsive. The nature of the non-compliance has not however, precluded an examination of the application on the merits, the results of which are communicated below.

#### **35 USC 101 Rejections**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 5, 7-9, 19-21, 23, 25-27, 36-38 and 40-41 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The inducible gene expression system reads on a cell infected with a retrovirus such as a HTLV-1 virus. The "inducible gene expression system" is defined as comprising a first

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vector comprising at least one retroviral promoter (applicants define a "vector" as any genetic element which can include a retrovirus virion, see page 7 of the instant specification), a factor which can induce a retroviral promoter (i.e. Tax, which is naturally produced by the virus) and at least one gene product expressed in proportion to retroviral promoter induction (i.e. the gene products expressed from the HTLV-1 LTR Tax responsive promoter). Retroviruses such as HTLV-1 also contain a RNA export element (i.e. sequences encoding Rex proteins) and they contain means for exogenous induction of the retroviral promoter or means for inducing the retroviral promoter from another vector (which can be another virion) in that the vector contains a inducible promoter which can be induced by a compound such as Tax produced from another virion in the same cell or a different neighboring cell. Since the claimed inducible gene expression system reads on naturally infected cells, said invention reads on a product of nature.

### **35 USC 102 Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7-9, 13-21, 25-27, 31-37 and 40-42 are rejected under 35

U.S.C. 102(b) as being anticipated by Kingsman et al.

Applicants claim an inducible gene expression system comprising: a first vector (which can be a retroviral vector, AAV vector, plasmid, etc.) comprising at least one retroviral promoter (which can be from HTLV-1); at least one factor (which can be Tax) to induce the retroviral promoter; and at least one gene product expressed in proportion to retroviral promoter induction.

Kingsman et al. (US 6,096,538, published 8/1/2000, see whole document, particularly Figs. 2-4; column 2, line 26 to column 4, line 46; column 7, line 6 to column 8, line 27) recites an inducible gene expression system comprising a vector (which can be a retroviral vector, AAV vector, plasmid, etc.) comprising at least one inducible retroviral promoter, at least one factor (which can be HIV tat or HTLV-1 Tax) to induce the promoter and at least one gene product (anything operably linked to the inducible retroviral promoter) expressed in proportion to the retroviral promoter induction. The factor (i.e. tat or Tax, etc.) can be delivered exogenously by a second vector (i.e. a HIV virion infected cell which produces tat which subsequently activates a tat responsive promoter on the first vector construct). Kingsman et al. also discloses a method comprising; providing a first vector comprising at least one retroviral promoter; providing at least one factor, inducing the retroviral promoter with the at least one factor; and expressing at least one protein based on the induction of the retroviral promoter. With regard to claim 18, the different components of the expression system must be in separate containers prior to being combined and hence Kingsman et al. teaches a kit comprising at least a portion of the expression system. Kingsman et al. therefore teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 13-14, 18-25, 31-32 and 36-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al.

Applicants' invention is as described above. Additionally, applicants claim a pseudotyped vector wherein the first vector comprises an RNA export element (such as a woodchuck mRNA processing enhancer, which can be a WPRE element) and a method of using said vectors.

Chang et al. (6,835,568, issued 12/28/2004, filed 10/30/2001, see whole document, particularly columns 1, 6-14 and claims 1-19) recites an inducible gene expression system comprising: a first vector (which can be a pseudotyped retroviral or AAV or adenoviral, etc. vector in a cell) comprising at least one retroviral promoter (i.e. a tat regulatable retroviral promoter); at least one factor (which can be tat) to induce the retroviral promoter; and at least one gene product expressed in proportion to retroviral promoter induction. The gene expression system disclosed by Chang et al. can also contain an RNA export element (i.e. Rev, Rev responsive element) and a woodchuck mRNA processing enhancer (i.e. woodchuck hepatitis virus PRE (WPRE)). The factor which induces the promoter can be supplied exogenously in the form of a second vector

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(i.e. a HIV virion expressing tat protein). Chang et al. also recites a method for expressing a gene product of interest comprising using the aforementioned gene expression system. With regard to claim 18, the different components of the expression system must be in separate containers prior to being combined and hence Chang et al. teaches a kit comprising at least a portion of the expression system. Chang et al. therefore teaches the claimed invention.

### **35 USC 112, 2<sup>nd</sup> Paragraph Rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 15, 19-35 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 15, 20 and 33 are vague in that applicants recite that the "vector comprises a host cell". Applicants' definition of a "vector" on p. 7 of the instant specification does not include a "host cell" and it is unclear how a vector, which applicants define as a nucleic acid molecule, virion, plasmid, etc., can comprise a host cell.

Claim 19 (and dependent claims) are vague in the recitation of the phrase "factor corresponding to the retroviral promoter" as it is unclear what the relationship between the factor and the promoter is. Possibly applicants mean to recite a factor which induces the retroviral promoter.

### Objections to the Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The terminology "mRNA processing enhancer" and "woodchuck mRNA processing enhancer" is not found in the specification as filed.

No Claims are allowed.

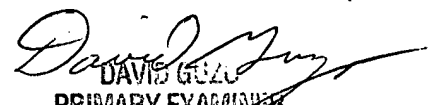
Claims 10-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
October 27, 2006

  
DAVID GUZO  
PRIMARY EXAMINER